

**REMARKS**

Applicants have cancelled claims 23 to 26 in this response.

Claims 10-22 and 27-38 were previously cancelled.

Claims 1-9 are now currently pending in the application.

**Claims Rejections – 35 USC § 103**

**(A)** Claims 1 to 6 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,277,311 to Hollister. (“Hollister 311”) in view of U.S. Patent No. 4,982,842 to Hollister (“Hollister 842”).

**(B)** Claims 3 and 4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister 311 in view of Hollister 842, and further in view of U.S. Patent No. 6,695,819 to Kobayashi. (“Kobayashi”).

**(C)** Claims 3 and 4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister 311 in view of Hollister 842, and further in view of U.S. Patent No. 6,440,104 to Newby et al. (“Newby”).

**(D)** Claims 7 and 23 to 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister 311 in view of Hollister 842, and Newby and further in view of U.S. Patent Application No. 2003/0028152 to Alesi et al. (“Alesi”).

**(E)** Claims 7 and 23 to 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister 311 in view of Hollister 842, and Kobayashi and further in view of U.S. Patent Application No. 2003/0028152 to Alesi et al. (“Alesi”).

**(F)** Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister 311 in view of Hollister 842, and further in view of U.S. Patent No. 5,681,295 to Gyure et al. (“Gyure”).

These rejections are respectfully traversed in view of this amendment.

Of the claims rejected, claims 23-26 have been cancelled, claim 1 is independent, with the claims 2-9 dependent thereon.

Claim 1 recites a holder assembly comprising among other things:

*a safety shield pivotably attached to a collar, said collar having an opening therethrough for receiving a needle cannula therethrough, the collar being received between the annular skirt and the needle receiving port of the holder housing such that the safety shield is capable of being pivoted over at least a portion of a needle received within the needle receiving port of the holder housing,*  
*wherein the safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port around the axis of the holder housing without axial movement of the collar along the axis.*

There is no suggestion of an annular skirt in Hollister 311 let alone to locate a mounting collar between an annular skirt and a needle receiving port of the holder housing.

The Examiner also notes in the office action of August 5, 2008 that Hollister 311 “fails to explicitly teach an annular skirt.”

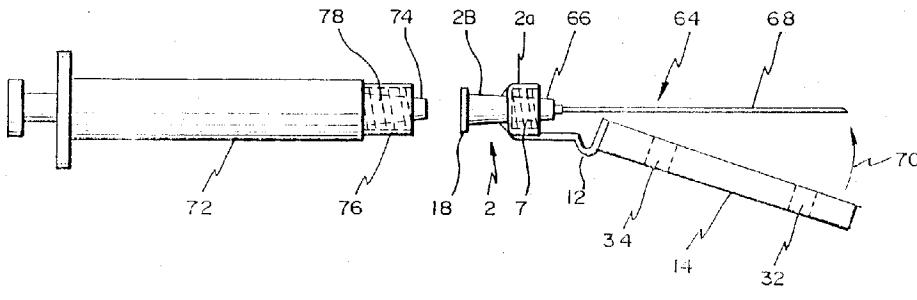
In contrast, Hollister 311 teaches a collar (18) mounted on the outer surface of the boss (16) (or needle receiving port) of the holder (2).

It would require a complete redesign of the holder housing of Hollister 311 in order to be able to locate the mounting collar between an annular skirt and a needle receiving port.

In addition, there is no suggestion in Hollister 842 that the safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port around the axis of the holder housing without axial movement of the collar along the axis.

Hollister 842 is relied on for the disclosure of holder assembly comprising an annular skirt extending about a receiving port.

Hollister 842 teaches a luer lock syringe 72 which has an internally threaded collar 76 surrounding its male luer 74. Extension 18 at the end of section 2b is used to threadedly mate with thread 78 at the inner circumference of collar 76.



**FIG. 4**

In contrast to the claimed invention, a radial rotation of the safety shield and collar of Hollister 842 about an axis of the holder housing would inevitably result in axial movement of the collar along the axis as extension 18 would travel along thread 78 in an axial direction.

Furthermore, Hollister 842 teaches away from any radial rotation of the safety shield and collar during use, due to the possibility of leakage occurring between the luer interface of male luer 74 and section 2B, thus rendering the device inoperable.

Thus Hollister 842 alone or in combination with Hollister 311 fails to teach or suggest the attachment location of a collar between the annular skirt and needle receiving port of the holder housing, wherein the safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port around the axis of the holder housing without axial movement of the collar along the axis.

Accordingly, it is submitted that the holder assembly as defined by claim 1 is not taught or suggested by the cited references. In addition, claims 2-9 being dependent on claim 1 are likewise patentable over the cited references.

In rejections (B) (C) (D) (E) and (F) the Examiner in addition to Hollister 311 in view of Hollister 842 cites Kobayashi, Newby, Alesi, and Gyure.

Kobayashi, Newby, Alesi, and Gyure do not overcome the deficiencies of Hollister 311 in view of Hollister 842 when considered in combination or individually, as explained above in connection with rejection (A) of claim 1.

Kobayashi and Newby, are relied on only for the disclosure of a hanger bar is part of the safety shield and the hook arm is part of the collar. Alesi is used to show disclosure of a living hinge attached to an annular skirt, while Gyure is only used to show the disclosure of a collar having one or more slits in a rearward portion.

Therefore applicant submits that the claims listed in rejections (B) (C) (D) and (E) being dependent on claim 1, are patentable over the cited references.

**Conclusion**

In view of the remarks and amendments herein, applicant submits the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicant's agent at the telephone number set forth below.

Respectfully submitted,

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